MED CERT®

Certification. Medical Only.

Certificate

The Certification Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 — 20355 Hamburg — Germany

herewith confirms that the company

TimeWaver Production GmbH
Schloss Kränzlin, Darritzer Strasse 6
16818 Kränzlin
Germany

has introduced, applies and maintains a Quality Management System in the area of:

Manufacture, final inspection and distribution of

- **electro stimulation devices**
- **devices for skin resistance measurement**

The compliance of the Quality Management System with the requirements of the below mentioned standard was verified by an audit:

EN ISO 13485:2012 + AC:2012

This certificate is valid until: 21 November 2016

Report No.: 7156PS04F
Process No.: QS - 7156
Certificate No.: 7156GB438151203

Hamburg, 03 December 2015

MEDCERT Certification Body
(Markus Bianchi)

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-19630-04-00

MED CERT®

Certification. Medical Only.

EC-Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith confirms that the company

TimeWaver Production GmbH
Schloss Kränzlin, Darritzer Strasse 6
16818 Kränzlin
Germany

has introduced, applies and maintains a Quality Assurance System **concerning the conformity of the medical devices with the metrological requirements** for the products / product categories:

Devices for skin resistance measurement

The compliance of the Quality Assurance System with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex V

This certificate is valid until: 21 November 2016

Report No.: 7156PS04F
Process No.: QS - 7156
Certificate No.: 7156GB416151203

Hamburg, 03 December 2015

MEDCERT Certification Body
(Markus Bianchi)

MEDCERT Identification No.: 0482

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

EC-Declaration of Conformity

Within the meaning of

Council Directive 93/42 EEC of 14 June 1993 concerning medical device

It is a medical device of Class IIa.

Brand: **TimeWaver Med**

The product is designed and manufactured according to Directive 93/42/EEC under sole responsibility of:

Firma: TimeWaver Production GmbH
Schloss Kränzlin
Darritzer Strasse 6
16818 Kränzlin

The technical documentation with risk analysis is completely available. This declaration is valid for at least 1 year after signing, at the latest until the expiry of the Annex-V-Certificate.

The product meets the essential requirements. The directions concerning the product are available. The conformity assessment procedure was carried out in accordance with Annex V and Annex VII to Directive 93/42/EEC.

The Notified Body is **MedCert,** Pilatuspool 2, Hamburg, Germany, with the identification number 0482.

The product complies with the applicable standards listed in the central list of standards of TimeWaver Production GmbH.

Kränzlin, 23.12.2015

Place, date

TimeWaver PRODUCTION GmbH
Schloss Kränzlin · Darritzer Str. 6 · D-16818 Kränzlin
Tel. +49(0)3391-4002212 · Fax 03391-4002299
Email: prod@timewaver.de · www.timewaver-med.de

CEO

CE 0482

Version 03. 12-2015

EC-Declaration of Conformity

Within the meaning of

Council Directive 93/42 EEC of 14 June 1993 concerning medical device

It is a medical device of Class IIa.

Brand: **TimeWaver Frequency**

The product is designed and manufactured according to Directive 93/42/EEC under sole responsibility of:

Firma: TimeWaver Production GmbH
Schloss Kränzlin
Darritzer Strasse 6
16818 Kränzlin

The technical documentation with risk analysis is completely available. This declaration is valid for at least 1 year after signing, at the latest until the expiry of the Annex-V-Certificate.

The product meets the essential requirements. The directions concerning the product are available. The conformity assessment procedure was carried out in accordance with Annex V and Annex VII to Directive 93/42/EEC.

The Notified Body is **MedCert,** Pilatuspool 2, Hamburg, Germany, with the identification number 0482.

The product complies with the applicable standards listed in the central list of standards of TimeWaver Production GmbH.

Kränzlin, 23.12.2015

Place, date

TimeWaver PRODUCTION GmbH
Schloss Kränzlin · Darritzer Str. 6 · D-16818 Kränzlin
Tel. +49(0)3391-4002212 · Fax 03391-4002299
Email: prod@timewaver.de · www.timewaver-med.de
CEO

CE 0482

Version 03, 12-2015

EC-Declaration of Conformity

Within the meaning of

Council Directive 93/42 EEC of 14 June 1993 concerning medical device

It is a medical device of Class IIa.

Brand: **TimeWaver Home**

The product is designed and manufactured according to Directive 93/42/EEC under sole responsibility of:

Firma: TimeWaver Production GmbH
Schloss Kränzlin
Darritzer Strasse 6
16818 Kränzlin

The technical documentation with risk analysis is completely available. This declaration is valid for at least 1 year after signing, at the latest until the expiry of the Annex-V-Certificate.

The product meets the essential requirements. The directions concerning the product are available. The conformity assessment procedure was carried out in accordance with Annex V and Annex VII to Directive 93/42/EEC.

The Notified Body is **MedCert,** Pilatuspool 2, Hamburg, Germany, with the identification number 0482.

The product complies with the applicable standards listed in the central list of standards of TimeWaver Production GmbH.

Kränzlin, 23.12.2015

Place, date

TimeWaver PRODUCTION GmbH
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Email: prod@timewaver.de · www.timewaver-med.de

CEO

CE 0482

Version 03. 12-2015

EC-Declaration of Conformity

Within the meaning of

Council Directive 93/42 EEC of 14 June 1993 concerning medical device

It is a medical device of Class Im.

Brand: **ReguScope**

The product is designed and manufactured according to Directive 93/42/EEC under sole responsibility of:

Firma: TimeWaver Production GmbH
Schloss Kränzlin
Darritzer Strasse 6
16818 Kränzlin

The technical documentation with risk analysis is completely available. This declaration is valid for at least 1 year after signing, at the latest until the expiry of the Annex-V-Certificate.

The product meets the essential requirements. The directions concerning the product are available. The conformity assessment procedure was carried out in accordance with Annex V and Annex VII to Directive 93/42/EEC.

The Notified Body is **MedCert,** Pilatuspool 2, Hamburg, Germany, with the identification number 0482.

The product complies with the applicable standards listed in the central list of standards of TimeWaver Production GmbH.

Kränzlin, 23.12.2015

Place, date

TimeWaver PRODUCTION GmbH
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Version 01, 12-2015